DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 2, 2014

Emerge Medical
Ms. Michelle Potvin
Vice President of Quality Assurance
720 South Colorado Boulevard, Suite 550-S
Denver, Colorado 80246

Re: K141347
Trade/Device Name: Emerge Medical IM Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: August 29, 2014
Received: September 2, 2014

Dear Ms. Potvin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K141347

Device Name: **Emerge Medical IM Nail System**

Indications for Use:

The Emerge Medical IM Nail System is intended to provide temporary stabilization in long bones including the femur, tibia and humerus of various types of open or closed fractures including malunions, nonunions (pseudoarthrosis), correction osteotomy including malalignment, pathologic fractures, impending pathologic fractures, and tumor resections of specific bones.

Specific Femoral indications may include supracondylar fractures, including those with intra-articular extension, Ipsilateral femur fractures, fractures proximal to a total knee arthroplasty, and fractures distal to a hip joint.

Specific Humeral indications according to AO classification may include Type A-Fractures, dislocated, Type B Fractures, dislocated, Type C-Fractures, with intact calotte, or Humeral Fractures according to Neer-Classification.

Prescription Use X or Over-The-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K141347

510(k) Summary

NAME OF FIRM:	Emerge Medical 720 S. Colorado Blvd. Suite 550-S Denver, CO 80246
DATE PREPARED:	September 18, 2014
510(K) CONTACT:	Michelle Potvin Vice President of Quality Assurance Tel: (720) 459-6392
PROPOSED TRADE NAME:	Emerge Medical IM Nail System
DEVICE CLASSIFICATION:	Class II; 21 CFR 888.3020
CLASSIFICATION NAME:	Intramedullary fixation rod
PRODUCT CODE:	HSB
DEVICE DESCRIPTION:	The System consists of titanium alloy intramedullary (IM) nails, locking screws and end caps. The rigid, cannulated IM nails are inserted into the medullary canal and available in a variety of styles and lengths with proximal and distal holes for locking screws.
INDICATIONS FOR USE:	The Emerge Medical IM Nail System is intended to provide temporary stabilization in long bones including the femur, tibia and humerus of various types of open or closed fractures including malunions, nonunions (pseudoarthrosis), correction osteotomy including malalignment, pathologic fractures, impending pathologic fractures, and tumor resections of specific bones. Specific Femoral indications may include supracondylar fractures, including those with intra-articular extension, Ipsilateral femur fractures, fractures proximal to a total knee arthroplasty, and fractures distal to a hip joint. Specific Humeral indications according to AO classification may include Type A-Fractures, dislocated, Type B Fractures, dislocated, Type C-Fractures, with intact calotte, or Humeral Fractures according to Neer-Classification.
MATERIALS:	Titanium alloy (ASTM F136)
PREDICATE DEVICES:	Stryker IM Nails (K081152, K003018, K043404); Emerge Medical Screws (K122489, K140119)
TECHNOLOGIC CHARACTERISTICS:	The fundamental scientific principles and technological characteristics, including the intended use, material, general design, and sizes of the devices are equivalent to the predicate devices.
PERFORMANCE DATA:	Dimensional analysis and mechanical testing (ASTM F-1264 and ASTM F-543) demonstrated that the device performs as well as or better than the predicate device. Clinical data were not needed to demonstrate substantial equivalence.